English, human-only abstracts from January 1, 1992 to December 31. **RESULTS:** Quality of life evaluations for the following compounds were included in the review: abiraterone, cabazitaxel, docetaxel, enzalutamide, mitoxantrone, radium-223, samarium-153, and strontium-89. Significantly greater quality of life response was observed in the enzalutamide population compared to placebo (43% vs. 18%) while docetaxel showed significant difference in a head-to-head comparison with mitoxantrone on pain response (31-35% vs. 22%) as measured by the McGill questionnaire. Cabazitaxel did not show a significant difference in pain response compared to mitoxantrone. Abiraterone showed significant difference in multiple outcomes: pain palliation (44% vs. 27%) as measured by BPI-SF; reduction in fatigue intensity (58% vs. 40%) as measured by BFI; and time to HRQoL degradation (12.7 vs. 8.3 months) as measured by FACT-P. Abiraterone is the only agent reviewed to be effective in survival, pain palliation and progression and HRQoL. Additionally, abiraterone uniquely measured and showed benefit in fatigue. No patient-reported outcomes were pursued for sipuleucel-T. EORTC QLQ-C30 and FACT-P were the most common HRQoL instruments used. **CONCLUSIONS:** Studies in mCRPC typically include endpoints for pain palliation and quality of life improvement. Additionally, novel therapies are focusing on pain associated with bone metastases. There is no standard HRQoL or pain instrument being consistently used across prostate cancer trials.

PCN106

PATIENT-REPORTED OUTCOMES (PROS) CLAIMS IN PRODUCTS INDICATED FOR TREATMENT OF NON-SMALL-CELL LUNG CARCINOMA AND APPROVED IN EUROPE AND IN THE UNITED STATES

Caron M, Emery MP, Acquadro C, Excanez-Virieux MP
MAPI Research Trust, Lyon, France

OBJECTIVES: 1) To identify products indicated for treatment of non-small-cell lung carcinoma (NSCLC) approved with a PRO labeling claim in Europe and the US; and (2) to list the differences found in Europe versus the US in terms of products and labeling. **METHODS:** The search was performed on the Food and Drug Administration (FDA) and European Medicines Agency (EMA) approved medicinal product labels and on the FDA medical reviews and EMA scientific discussions. **RESULTS:** A total of 15 products (generics excluded) were identified, six at the EMA and nine at the FDA. The six products approved by the EMA were also approved by the FDA. Four products with a PRO claim were identified in Europe (i.e., docetaxel, erlotinib, gefitinib and paclitaxel), and two in the US (i.e., paclitaxel and gemcitabine). Most of the PROs identified in the claims were quality of life and symptoms. For four products (i.e., docetaxel, erlotinib, gefitinib and paclitaxel), the EMA and FDA showed disagreement in terms of PRO labeling. The EMA gave a PRO claim (quality of life and symptom) to three products, but not the FDA; for paclitaxel, the FDA did not include quality of life in the label. Except for gefitinib, the reviews of both agencies were conducted on the same clinical studies. The analysis of the medical reviews and scientific discussions showed that FDA did not include the PROs in the label because of concerns about the quality of the study design, of the analyses, or the questionnaires' content validity. **CONCLUSIONS:** Our review showed that the patients' perspective in the treatment of non-small-cell lung carcinoma is important for the EMA and FDA. However, differences exist in the evaluation of PRO data for inclusion in the label. Our analysis suggests a higher receptivity of EMA to quality of life as a global concept.

PCN107

PATIENT REPORTED OUTCOMES IN CHRONIC MYELOID LEUKEMIA: A SYSTEMATIC REVIEW

Aggarwal S, Segal J, Messenger M
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). Chronic myeloid leukemia (CML) is now a chronic disease in which HRQoL is becoming important. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with CML. **METHODS:** A systematic literature search for CML randomized controlled trials (RCTs) with PROs endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar, and Cochrane. Data was collected for the study size, interventions, year, PRO instrument, and results for PROs. Analysis was conducted to identify trends in commonly used PRO instruments and results were categorized as positive, neutral, or negative. **RESULTS:** Eight RCTs with a total of 3342 patients were identified. In these studies, there were eight different PROs instruments identified: FACT-Leu, SF-36, FSI, PSQI, MSAS-SF, FACT-BRM, EQ-5D, and MDASI-CML. The most commonly used instruments were FACT-Leu (used in 1336 patients) and FACT-BRM (used in 1199 patients). Five studies reported positive results with improvement in quality of life (QoL) symptoms versus comparator treatments. Two studies reported results highlighting significant deterioration in QoL versus patients with no cancer. One study reported QoL in various types of CML and showed significant deterioration in patients with chronic phase CML versus those with acute and blast phase CML. Studies also identified two QoL domains, depression and fatigue, which matter most for patients with CML. **CONCLUSIONS:** Patients with CML have significant deterioration in their QoL. PRO instruments such as FACT-Leu and FACT-BRM can aid in generating evidence to show which therapies improve patient QoL.

PCN108

ELECTRONIC VERSUS PAPER-BASED DATA COLLECTION TO ASSESS PATIENT-REPORTED OUTCOMES

Agarwal P, Tworek C
West Virginia University School of Pharmacy, Morgantown, WV, USA

OBJECTIVES: With increasing interest in patient-reported outcomes and technological advances, the mode of data collection has shifted focus from paper-based self-administered surveys to computerized electronic device-assisted surveys. The study purpose was to examine differences in quality of data collected, via paper-based vs. electronic web-based surveys delivered via an iPod among cancer patients in West Virginia. **METHODS:** Convenience sampling was used to recruit participants from the Mary Babb Randolph Cancer Center (MBRCC) in Morgantown, WV. Eligible respondents were: adults 18 years and above; receiving treatment or scheduled for follow-up at MBRCC following cancer diagnosis; fluent in English; and consented to participate. Respondents were screened and no information was retained from those who refused or were ineligible. The study was approved by West Virginia University Institutional Review Board. Electronic web-based data were saved to a secure server in SPSS software format. Data from paper-based surveys were collected and manually entered into a SPSS database. **RESULTS:** There were 87 electronic web-based survey responses; however, due to technical issues, only 67 had complete data. This missing pattern occurred in the first 20 surveys, although electronic survey design did not allow skipping questions. Responses for 101 paper-based surveys were recorded with no unique missing pattern identified; however, 12 respondents skipped the income question, resulting in missing demographic data. Web-based surveys handled skip patterns better, with more accurate data collection; however, respondents reported difficulties in iPod data collection, such as small screen size and difficulty using the slide bar. **CONCLUSIONS:** Despite widespread interest and increasing use, electronic handheld data collection devices should be used with caution. Technical problems with internet connectivity and missing data submission to web-based servers may be limitations. Electronic data collection may also be less appropriate for specific subpopulations, such as the elderly, or those unfamiliar with computer technology.

PCN109

NOVEL ELECTRONIC PATIENT REPORTED OUTCOMES TOOL FOR PROSTATE CANCER PATIENTS

Aggarwal S, Topaloglu H
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Patient Reported Outcomes (PROs) play an important role in evaluating patient quality of life and comparative efficacy of various treatments. Another potential use of PROs is for chronic disease management, which can provide useful data to physicians and patients. We developed a novel web and phone based PROs tool for management of prostate cancer disease. **METHODS:** PRO methods for prostate cancer were reviewed by analyzing published clinical studies. KOLs and patient advocacy groups were interviewed to obtain their input for design of PRO disease management tool. Recent technologies for developing such tools were reviewed by analyzing available electronic PRO tools. PROCDIM design was developed based on secondary research and primary interviews. **RESULTS:** PROCDIM was designed to capture patient reported outcomes data such as Quality of Life (using five attributes), adverse events (six commonly reported AEs), medications and OTC drugs history, PSA antigen score, past surgery and radiation therapy, and record of physician appointments. Patients could enter data into PROCDIM using web or phone (iphone or andriod) based systems. Data from PROCDIM could be emailed by the patient to the provider or could be downloaded by tethering a phone to a computer. Pilot data was captured by testing PROCDIM with physicians and patient advocacy groups. Based on interviews, PROCDIM was rated superior and highly user friendly compared to current chronic disease management tools. Patient outcomes data would be collected from a planned IRB approved study. **CONCLUSIONS:** PROCDIM is a valuable tool to capture several patients reported outcomes and data for chronic disease management. Such tools could be used for collecting data for disease management, clinical trial, and observational studies for various chronic diseases.

PCN110

PATIENT PREFERENCES: UNDERSTANDING RISK-BENEFIT TRADE-OFFS OF GENOMIC TESTING IN CHEMOTHERAPY DECISIONS FOR BREAST CANCER PATIENTS

Marshall D[1], Bombard Y[2], Trudeau M[3], Leighl N[4], Pykerman K[5], Deal K[6]
[1]*Alberta Bone & Joint Health Institute, Faculty of Medicine, University of Calgary and Principal Consultant, Optuminsight, Calgary, AB, Canada,* [2]*Yale University, New Haven, CT, USA,* [3]*Sunnybrook Health Science Centre, Toronto, ON, Canada,* [4]*Princess Margaret Hospital, Toronto, ON, Canada,* [5]*University of Calgary, Calgary, AB, Canada,* [6]*McMaster University, Hamilton, ON, Canada*

OBJECTIVES: Gene expression profiling (GEP) of tumours informs baseline risk prediction, potentially affecting decisions about adjuvant chemotherapy for women with early breast cancer (BrCa), of whom only 15% will experience a recurrence. Limited evidence exists on the clinical utility of GEP in chemotherapy treatment decisions. We aimed to measure the value of GEP testing information in chemotherapy treatment decisions based on risk-benefit tradeoffs from a stated preferences study. **METHODS:** Based on literature review, focus groups and interviews with BrCa patients and medical oncologists, we developed a discrete choice experiment survey. For our pilot, we surveyed BrCa patients (n=27), women from the general public (n=55), and medical oncologists (MOs; n=3) across Canada. The DCE included 12 choice tasks with 5 attributes and 3 scenario profiles considering orthogonality, D-efficiency and level balance. Preferences were analyzed using conditional logit and hierarchical Bayes and evaluated for goodness-of-fit. **RESULTS:** Most (>80%) respondents know someone who had chemotherapy for cancer. However, few respondents (<10%) know someone who had GEP testing. Across the three groups, the most important attributes in chemotherapy treatment decisions were (in order): GEP